UNITED S ES DEPARTMENT OF COMMERCE
Patent and ..demark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/488,180

| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|---|---|---|---|
| 08/488,180 | 06/07/95 | CARTER P | W SYN-51-CY/JPW |

18M1/0402

JOHN P WHITE
COOPER AND DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

| EXAMINER | |
|---|---|
| SCHEINER, T | |
| **ART UNIT** | **PAPER NUMBER** |
| 1806 | 3 |

**DATE MAILED:** 04/02/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on June 7, 1995.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☑ Claim(s) 13-18 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 13-18 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☑ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☑ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☑ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**

**Part III DETAILED ACTION**

Claims 1-12 have been canceled by preliminary amendment. Claims 13-18 are pending in the application.

*Claim Rejections - 35 USC § 112*

Claims 16-18 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of the hybridoma cell lines secreting monoclonal antibodies OD3 (HB 10204), NB-3 (HB 10205), and TA-1 (HB 10206) While the specification provides enough information for one of skill in the art to produce hybridoma cell lines secreting antibodies with the same or similar properties as monoclonal antibodies OD3, NB-3 and TA-1, reproduction of the identical cell lines and antibodies is an unpredictable event. Because it does not appear that monoclonal antibodies OD3, NB-3 and TA-1 are known and publicly available or can be reproducibly isolated from nature without undue experimentation, and because claims 16-18 specifically require hybridoma cell lines secreting monoclonal antibodies OD3, NB-3 and TA-1, a suitable deposit of the hybridoma cell lines is required for patent purposes.

Applicants' referral to the deposit of HB 10204, HB 10205 and HB 10206 on page 9 of the specification is insufficient assurance that all of the conditions of 37 CFR §§ 1.801-1.809 have been met.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants or assignees, or a statement by an attorney of record over his or her signature and registration number, stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

maintain for 13, 15

Claims 13 and 15-18 are rejected under 35 U.S.C. § 102(a) as being anticipated by McKenzie *et al.* (Oncogene, vol. 4, no. 5, pp. 543-548, May 1989).

McKenzie *et al.* disclose hybridoma cell lines secreting OD3 (HB 10204), NB-3 (HB 10205), and TA-1 (HB 10206), all of which bind the extracellular domain of the human *neu* gene product. The first parent application of the instant application to disclose this series of hybridomas cell lines and monoclonal antibodies appears to be serial no. 07/412,668, filed on September 29, 1989. The McKenzie *et al.* reference is prior art because its publication date is earlier than September 1989, and its authorship differs from the instant inventive entity.

Withdraw for 13, 15

Claims 13 and 15 are rejected under 35 U.S.C. § 102(a) as being anticipated by Masuko *et al.* (Jpn. J. Cancer Res., vol. 80, pp. 10-14, January 1989).

Masuko *et al.* disclose a hybridoma cell line secreting a monoclonal antibody (SV2-61) which recognizes the extracellular domain of the human *neu* gene product. See the abstract.

Claims 13 and 15 are rejected under 35 U.S.C. § 102(b) as being anticipated by Drebin *et al.* (Nature, vol. 312, no. 5994, pp. 545-548, December 1984) in light of Disis *et al.* (Journal of Immunology, vol. 156, no. 9, pp. 3151-3158, 1996).

Drebin *et al.* disclose hybridoma cell lines which secrete monoclonal antibodies that react specifically with cell-surface (i.e., extracellular) determinants found on NIH 3T3 cells transfected with rat neuroblastoma DNA. The antibodies bind to and immunoprecipitate a phosphoprotein of relative molecular mass 185,000 (p185, the rat *neu* protein). Disis *et al.* are cited to show that the protein product of the rat *neu* gene is approximately 89% homologous to the human HER-2/neu protein (note that this reference is cited as evidence of the similarity of the rat and human proteins, not as prior art). In view of the similarity between the rat and human proteins, Drebin *et al.*'s antibodies are "capable of binding to p100 which is a human neu related protein . . . [which] corresponds substantially to the extracellular domain of the human neu gene product" and thus anticipate the instantly claimed hybridoma and monoclonal antibody.

### *Claim Rejections - 35 USC § 103*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

mainfair

Claim 14 is rejected under 35 U.S.C. § 103 as being unpatentable over McKenzie *et al.* (Oncogene, vol. 4, no. 5, pp. 543-548, May 1989).

McKenzie *et al.* disclose hybridoma cell lines secreting OD3 (HB 10204), NB-3 (HB 10205), and TA-1 (HB 10206), all of which bind the extracellular domain of the human *neu* gene product. The reference differs from the instant invention in not disclosing immunoreactive fragments of the monoclonal antibodies. However, it is conventional to prepare fragments of antibodies for use in

diagnostic assays, and it would have been obvious for one of ordinary skill in the art to have prepared fragments of McKenzie *et al.*'s antibodies.

Claim 14 is rejected under 35 U.S.C. § 103 as being unpatentable over Drebin *et al.* (Nature, vol. 312, no. 5994, pp. 545-548, December 1984) (in light of Disis *et al.* (Journal of Immunology, vol. 156, no. 9, pp. 3151-3158, 1996)) as applied to claims 13 and 15 above.

Drebin *et al.* disclose as set forth above, but differ from the instant invention in not disclosing immunoreactive fragments of monoclonal antibodies capable of binding the extracellular domain of the human *neu* protein. However, it is conventional to prepare fragments of antibodies for use in diagnostic assays, and it would have been obvious for one of ordinary skill in the art to have prepared fragments of Drebin *et al.*'s antibodies.

Claims 14 and 16-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Masuko *et al.* (Jpn. J. Cancer Res., vol. 80, pp. 10-14, January 1989).

Masuko *et al.* disclose a hybridoma cell line secreting a monoclonal antibody (SV2-61) which recognizes the extracellular domain of the human *neu* gene product. See the abstract.

With respect to claim 14, Masuko *et al.* differ from the instant invention in not disclosing immunoreactive fragments of monoclonal antibodies capable of binding the extracellular domain of the human *neu* protein. However, it is conventional to prepare fragments of antibodies for use in diagnostic assays, and it would have been obvious for one of ordinary skill in the art to have prepared fragments of Masuko *et al.*'s antibodies. With respect to claims 16-18 Masuko *et al.* differ from the instant invention in disclosing monoclonal antibody SV2-61, rather than the instantly recited monoclonal antibodies OD3 (HB 10204), NB-3 (HB 10205), and TA-1 (HB 10206). However, SV2-61 recognizes the extracellular domain of the human *neu* gene product, and so has essentially the same binding properties as OD3, NB-3 and TA-1. It would have been obvious for one of ordinary skill in the art to make other, patentably indistinguishable, antibodies to the extracellular domain.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

3/27/97

Toni R. Scheiner

TONI R. SCHEINER
PRIMARY EXAMINER
GROUP 1800